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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,862	07/12/1999	PHILIP E. THORPE	4001.002282	1339

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/351,862	Applicant(s) THORPE ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 34-43* is/are pending in the application.

4a) Of the above claim(s) *2,13,15-18,30 and 36-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-12,16,19-29,34,35 and 39-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2,13,15-18,30 and 36-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *21, 24-2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Amendment filed on June 20, 2002 has been entered. Claims 1-30, 34-43 are pending.

Claims 2, 13, 15-18, 30, 36-38 are withdrawn from further consideration, as being drawn to a nonelected species. Applicant timely traversed the restriction (election) requirement in Paper No. 14. Claims 1-30, 34-43 are pending, however, claims 1, 3-12, 14, 19-29, 34-35, 39-42 are under consideration at this time.

This application contains claim 2, 13, 15-18, 30, 36-38 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP 821.01.

Response to Amendment

Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendments and Arguments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-12, 14, 19-22, 39-43 stand rejected under 35 U.S.C. 102(e) as being anticipated by Schroit US Patent 6,300,308.

Applicant's arguments with respect to this rejection have been fully considered but they are not persuasive.

The instant claims are directed to kits containing at least a first aminophospholipid antibody or antigen-binding fragment thereof in combination with an

detectably-labeled antibody or antigen-binding fragment thereof directed to aminophospholipid or anticancer agent. This claim is not limited to two distinct antibodies directed to aminophospholipids. The instant second anticancer agent encompasses any anticancer agent.

Applicant argues that the present kits are not directed to phosphatidylserine-polypeptide conjugates (Amendment at page 9). However, such conjugates are within the scope of an anticancer agent (see Schroit, claim 21).

Applicant also asserts that the Action's reference to antibody directed to "aminophospholipid receptors" is not understood. Examiner points out that Schroit teaches PS specific antibodies that can be conjugated with a polypeptide. Since, PS is an aminophospholipid, Schroit's antibodies are directed to aminophospholipid receptors.

Applicant asserts that Schroit teaches immunodetection reagents alone and there is no reference to any therapeutic agent. Examiner disagrees with Applicant's interpretation of Schroit. Col 7, line 67- col 8, line 1, states "In such cases, one or more containers would contain each of the PS composition(s).." Therefore, Schroit's discloses kits that can contain containers with a second anti-aminophospholipid antibody conjugate. Further, Schroit claims an antibody-therapeutic construct (see claim 21). Moreover, Schroit's antibody can exist in "separate moieties to be conjugated by user of the kit" (see col 6, lines 50-51). Thus, Schroit teaches PS antibody compositions are not only naked, but also can be used in combination with a therapeutic agent.

Applicant also argues that diphtheria toxoid of Schroit is a carrier for lipid immunization. In response, Examiner states that regardless of the intended use,

diphtheria toxoid of Schroit provides therapeutic activity within the scope of the instant claims. Accordingly, Schroit anticipates the limitations of the instant claims.

Claims 1, 3-12, 14, 19-29, 34-35, 39-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schroit US Patent 6,300,308 in view of Gimbrone US Patent 5,632,991 and Umeda (IDS, 9/19/1999).

Applicant's arguments with respect to this rejection have been fully considered but they are not persuasive.

The instant claims are directed to kits containing at least a first aminophospholipid antibody or antigen-binding fragment thereof in combination with an detectably-labeled antibody or antigen-binding fragment thereof directed to aminophospholipid or anticancer agent. The instant second anticancer agent encompasses any anticancer agent.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the combined teachings of the cited references renders the limitations of the present claims obvious.

First, as argued above, Examiner states in col 7, line 65-col 8,line 1 Schroit sets forth that multiple PS antibody compositions can be used in Schroit's kit. Therefore, Schroit's suggests kits that can contain containers with a second anti-aminophospholipid antibody conjugate. Further, applicant's assertion that the present

kits are not phophatidylserine-polypeptide conjugates are not persuasive, because the instant therapeutic constructs within the kits do not exclude such constructs as taught by Schroit.

In addition, Gimbrone and Umeda supplement the teachings of Schroit to further provide for a second anticancer agent or therapeutic agent. Therefore, all the limitations of the instant claims are taught.

Finally, the rejection is based on the combination of the teachings set forth in the cited references. Each reference is directed to specific receptor molecule on the surface of human vascular endothelial cells associated with vascularized tumor. Thus, they are viewed to be in the same field of endeavor and are considered combinable. Moreover, the compositions of Schroit, Gimbrone and Umeda are used for the same purpose. Accordingly, combining the compositions taught by each reference in order to form third composition that is to be used for very same purpose is *prima facia* obvious. see *In re Kerkhoven*, 205 USPQ 1069(CCPA) 1980. Therefore, claims stand rejected.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

ss
October 20, 2002